



# UNIVERSITEIT VAN DIE VRYSTAAT UNIVERSITY OF THE FREE STATE



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2003-02-19

DR AM VAN DER BIJL  
FARMOVS-PAREXEL  
INTERNAL POST BOX G6  
UNIVERSITY OF THE FREE STATE

Dear Dr van der Bijl

ETOVS NR 31/03

RESEARCHER: DR AM VAN DER BIJL

PROJECT TITLE: A RANDOMIZED, CONTROLLED, CROSSOVER STUDY ASSESSING THE EXERCISE PERFORMANCE IN ADULT MALE SMOKERS COMPARING ELECTRICALLY HEATED CIGARETTES, CONVENTIONAL CIGARETTES AND SMOKING. (FARMOVS 310/2002)

You are hereby informed that the following were approved by the Ethics Committee during their meeting held on the 18<sup>th</sup> February 2003:

- Protocol Final Version dated 05 February 2003
- English and Afrikaans Subject Information Sheets and Statements of Informed Consent dated 5 February 2003
- CV's of the following investigators: Drs van der Bijl, A Coetzee, F Burger, PJ Jordaan, FP le Roux, JH Potgieter, I Rossouw, J Terblanche
- Investigator's Brochure Edition 1.0 dated July 10, 2002
- Insurance Certificates

The Committee recommended that the following addition has to be made in the Informed Consent: "Smoking is harmful to your health".

Your attention is kindly drawn to the following:

- Failure to submit a progress report not later than one year after approval of the project may result in the termination of the study.
- That all extensions, amendments, serious adverse events, termination of a study etc have to be reported to the Ethics Committee
- It is compulsory in all relevant studies to obtain MCC-approval prior to commencement
- These documents have been accepted as complying with the Ethics Standards for Clinical Research based on FDA, ICH GCP and Declaration of Helsinki guidelines
- Translations of the Subject Information Leaflet and Consent Form have to be submitted prior to commencement of a study.

Will you please quote the Etovs number as indicated above in subsequent correspondence, reports and enquiries.

Yours faithfully,

  
For DIRECTOR: MEDICINE ADMINISTRATION

24.FEB.2003 12:15  
( ) FARMOVS-PAREXEL

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